



Biotech Daily

Tuesday October 13, 2026

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH DOWN: CURVEBEAM UP 15%; ACTINOGEN DOWN 14%**
- * **IDENTIFAI \$10m IPO FOR WINDROSE PRE-NATAL GENETIC TEST**
- * **CURVEBEAM WINS CHINA HIRISE CT APPROVAL**
- * **CORRECTION: EBR SYSTEMS**
- * **ORTHOCELL 'EXCELLENT 5 REMPLIR PROSTATECTOMY CASES DATA'**
- * **EUDAEMON RAISES \$3.75m FOR HYDROGEL CONDOM**
- * **PROTEOMICS: 'PROMARKER ENDO 90% SENSITIVITY, 71% SPECIFICITY'**
- * **PAINCHEK EXPANDS SABRA DEAL TO 23 AGED CARE SITES**
- * **ONCOSIL STARTS EU PHASE II 'PULSE' PANCREATIC CANCER TRIAL**
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- * **QUEENSLAND UNI TRIALS CERVICAL CANCER BLOOD TEST**
- * **NYRADA FDA FEEDBACK 'SUPPORTIVE' OF XOLATRYP STUDIES**
- * **NEUROSCIENTIFIC, FDA AGREE ON PHASE II STEMSMART TRIAL DESIGN**
- * **IMMUTEP NASDAQ MINIMUM BID PRICE COMPLIANCE**
- * **MESOBLAST 3.3m M-D, CMO OPTIONS, 671k BOARD STOCK AGM**
- * **LUMOS 18m M-D DOUG WARD PERFORMANCE RIGHTS AGM**
- * **KIRKMAN BELOW 5% OF BLS**
- * **JAGEN, BORI LIBERMAN TAKE 19% OF CERYVYN**

MARKET REPORT

The Australian stock market edged up 0.01 percent on Tuesday October 13, 2026, with the ASX200 up 0.7 points to 8,783.9 points. Six of the Biotech Daily Top 40 companies were up, 27 fell, six traded unchanged and one was untraded.

Curvebeam was the best (see below), up 0.3 cents or 15 percent to 2.3 cents, with 116.1 million shares traded. EBR was up 10.7 percent; Proteomics climbed 7.7 percent; Resmed rose 2.0 percent; with Avita, Orthocell and Prescient up by more than one percent.

Actinogen led the falls, down 0.7 cents or 13.7 percent to 4.4 cents, with 12.1 million shares traded. Amplia and Medical Developments lost more than nine percent; Racura was down 8.5 percent; Botanix, Clarity and Micro-X shed more than six percent; Imugene and Lumos were down more than five percent; Polynovo and Saluda fell more than four percent; 4D Medical, Clinuvel, Cyclopharm, Immutep, Optiscan and Telix were down three percent or more; Compumedics, Neuren and Starpharma shed two percent or more; Aroa, Artrya, Mesoblast, Nanosonics, Nova Eye and Pro Medicus were down one percent or more; with Cochlear, CSL, Envision and Imricor down by less than one percent.

IDENTIFAI GENETICS

Identifai was up as much as 25 percent to 25 cents following its \$10 million initial public offer at 20 cents a share to develop its Windrose pre-natal genetic testing.

Last month, the Sydney and Tel Aviv based Identifai said it expected to list on the ASX under the code 'ID1', with an indicative market capitalization of \$38.4 million and it was at the intersection of artificial intelligence (A.I.), genomics and preventative health "three of the most-watched investment themes of 2026" (BD: Sep 25, 2026).

Identifai said one blood sample, would test "hundreds of genetic anomalies ... on the foetus with results delivered earlier than the current genetic testing pathway".

The company said that current screening "can take 20 plus weeks and multiple invasive follow-ups before a parent gets an answer ... [and] three to six percent of all newborns worldwide are affected by a serious congenital or genetic disorder".

Today, Identifai said its chief executive officer was the Tel Aviv, Israel-based Eyal Miller, and the chief scientific officer Prof Noam Shomron was Tel Aviv University Medical School's head of functional genomics and inventor of the technology, with Yossi Bornstein co-founder and chair.

The company said the intellectual property was protected by 11 patent families in multiple jurisdictions including the US, China and Israel.

Identifai said the funds raised would be for "US laboratory readiness, assay validation, a planned multi-centre clinical validation study and further product development".

The company said Aesir Corporate acted as lead manager to the initial public offer.

Identifai said its initial focus was advancing US laboratory readiness and assay validation, including clinical laboratory improvement amendments (CLIA) certification requirements and progressing a planned 600-participant, US multi-centre clinical validation study.

Identifai closed up five cents or 25 percent to 25 cents with 3.3 million shares traded.

CURVEBEAM A.I.

Curvebeam says it has China National Medical Products Administration (NMPA) approval for its Hirise weight-bearing computed tomography imaging system.

Last year, Curvebeam said it had a 10-year, \$10 million deal with a joint venture of Chinese partners to commercialize its Hirise weight-bearing CT (BD: Oct 30, 2025).

At the time, Curvebeam said it had an intellectual property licence agreement with a joint-venture between Weihai, China's Shandong Weigao Haixing Medical Device Co Ltd and "other proven and experience Chinese commercialization partners".

Today, the company said the approval was achieved "on the early end of timeline expectations, advancing the commercialization timetable" under its joint-venture partnership.

Curvebeam said the approval triggered a further \$1 million equity investment under the agreement with Shandong Weigao Haixing Medical Device Co and that the shares would be issued at 40.5 cents each, consistent with the agreed subscription price.

The company said following NMPA approval it would "focus on progressing commercial launch activities, developing the distribution pipeline and supporting the introduction of Hirise to the Chinese market".

Curvebeam managing-director Greg Brown said China approval was "a major milestone". "NMPA approval moves us beyond regulatory preparation and into commercialization," Mr Brown said.

"This pivotal growth opportunity for Curvebeam will be backed by Hirise sales, local manufacturing and supply chain optimization," Mr Brown said.

Curvebeam was up 0.3 cents or 15 percent to 2.3 cents with 116.1 million shares traded.

CORRECTION: EBR SYSTEMS

Last night's edition incorrectly said that in the three months to September 30, 2026, the EBR Wise system was implanted in "about half of the average July-August number".

This was incorrect.

The single month of September was "about half of the average July-August number".

Biotech Daily apologizes unreservedly to EBR.

The Monday sub-editor was going to be publicly executed by a firing squad, but instead he has been severely admonished and terminated.

EBR was up 1.5 cents or 10.7 percent to 15.5 cents with 10.9 million shares traded.

ORTHOCELL

Orthocell says five patient cases show "excellent early functional recovery data" for Remplir in the recovery of erectile function and urinary continence post-prostatectomy.

In 2025, Orthocell said it had US Food and Drug Administration 510(k) clearance to for commercial distribution of Remplir for peripheral nerve repair; and later said Remplir had been used in about 100 surgical cases to assist the recovery of erectile function and urinary continence post-prostate cancer surgery (BD: Apr 4 Nov 20, 2025).

Today, Orthocell said "recovery of urinary continence was observed in the majority of patients, with two patients achieving pad-free continence by three to four months and a third achieving pad-free continence by six months".

The company said "the two patients who did not achieve full continence had pre-existing urinary symptoms prior to surgery".

Orthocell said "of the four patients with erectile function prior to surgery, one reported erectile function with oral medication alone at 12 months, while two reported partial erectile function with second-line treatment"; and one patient had not regained erectile function at the time of assessment.

Orthocell said all five patients had undetectable prostate specific antigen (PSA) levels at the time of reporting, including one patient who had a small amount of tumor tissue that could not be surgically removed.

The company said the five patients had "prostate cancer that had grown beyond the outer edge of the prostate", two had high-grade tumors and three had intermediate-grade tumors.

Orthocell said all patients had "cancers that were severe enough that extensive removal of prostate tissue was required, including the nerves on the affected side".

The company said the case studies showed "the surgical robot was able to successfully place Remplir over the prostate nerve regions in all five patients, with no technical difficulties or significant additional operative time reported".

Orthocell said no Remplir-related complications were reported during surgery or post-treatment 12-month follow-up.

The company said the case series would "inform the planned prospective clinical trial, which will investigate Remplir's potential to support a more consistent and earlier return of erectile function and urinary continence following radical robotic prostatectomy".

Orthocell managing-director Paul Anderson said the pilot program "did what a first series should ... it showed Remplir can be placed reliably in a difficult and variable nerve-sparing setting, and it provided early safety, usability and functional data".

"The next step is a larger, adequately powered, prospective trial to support use of Remplir in improving recovery of erectile function and continence after nerve-sparing robotic prostatectomy," Mr Anderson said.

Orthocell was up one cent or 1.5 percent to 68 cents.

EUDAEMON TECHNOLOGIES PTY LTD

Sydney's Eudaemon says it hopes to raise \$10 million to support commercialization of its 'world's first' hydrogel condom.

In July, Eudaemon said it raised \$3.75 million in an "oversubscribed" funding round to fund its manufacturing plant and prepare for pivotal clinical studies and US and European regulatory submissions, with commercialization by 2030 (BD: Jul 31, 2026).

Today, the company said it opened a manufacturing facility in Annandale, Sydney and had raised \$4.5 million in its 'oversubscribed' seed raise.

Eudaemon said it had begun a consumer campaign in Australia and the US "ahead of a targeted 2028 commercial launch".

The company said the condom was developed from research supported by the Bill & Melinda Gates Foundation and was 50 percent water, latex-free and "designed to more closely replicate the mechanical and thermal properties of human tissue".

Eudaemon said it had 61 granted patents, including in the US and China, and had completed an initial clinical study of the technology.

Previously, a company spokesperson told Biotech Daily the technology was invented by co-founder Prof Robert Gorkin at the University of Wollongong, with Nick Northcott as co-founding executive chair and Dr Simon Cook co-founding executive director.

Today, Eudaemon said the additional \$10 million funding round would be used to fund clinical trials, regulatory clearances, manufacturing scale-up and commercialization.

The company said 115 Capital would manage the raise and interested investors could contact Nick Northcott at: nick@eudaemontech.com or telephone 0417 610 557.

Eudaemon is a private company.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says its Promarker Endo shows sensitivity of 90 percent for stage IV endometriosis and 80 percent for stages II to IV, with specificity of 71 percent.

Last year, Proteomics said a 704-sample clinical validation cohort showed its Promarker Endo blood test had an overall 83 percent sensitivity and 95 percent specificity for endometriosis (BD: May 26, 2025).

Today, the company said it had successfully refined and independently validated the model underpinning its Promarker Endo blood test for endometriosis using 400 samples from the University of Oxford, after refinement of the initial model which was developed using samples from Melbourne's Royal Women's Hospital.

Proteomics said Promarker Endo was a mass spectrometry-based blood test that measured protein bio-markers and combined them with clinical factors in a statistical model to provide a risk profile for endometriosis.

The company said the test was intended to support clinical assessment of patients with symptoms suggestive of endometriosis.

Proteomics said specificity was 71 percent for each stage grouping because every comparison used the same control population and corresponding test result.

The company said Promarker Endo refinement and successful validation provided "a robust foundation to enable final assay deployment and preparation for clinical use".

Proteomics said it was expecting to make Promarker Endo commercially available by April 2027, subject to preparing the assay for clinical deployment, establishing clear reporting and follow-up guidance for clinicians, and completing applicable quality, accreditation and regulatory requirements.

Proteomics was up one cent or 7.7 percent to 14 cents.

PAINCHEK

Painchek says it has expanded its pain assessment contract with the Tustin, California-based Sabra Health Care to 21 additional aged care sites, taking the total to 23 sites.

In 2025, Painchek said it had US Food and Drug Administration approval for its adult pain assessment and monitoring application for smartphones and tablets; and this year, the company said Sabra Health would fund its pain management software for up-to 20,000 beds at 329 nursing, long-term care and senior housing facilities; and later, said it had two, three-year contracts with Sabra (BD: Oct 8, 2025; Apr 14, Jun 4, 2026).

Today, Painchek said the 23 sites were covered by five national operators within Sabra's senior housing portfolio and Sabra continued "to introduce Painchek to operators within its wider portfolio".

Painchek chief executive officer Karen Holzberger said the Sabra expansion showed "how we are turning established relationships into commercial contracts".

"Alongside expanding our Sabra footprint, we are progressing opportunities with additional assisted living and memory care operators," Ms Holzberger said.

Painchek fell 1.3 cents or 13.1 percent to 8.6 cents with 2.95 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has begun participating in the EU-funded, 'Pulse' phase II trial to assess repeat treatment with its pancreatic cancer device in 120 patients.

In July, Oncosil said its phosphorous-32 device was selected for use in the 120-patient, Pulse, phase II pancreatic cancer trial at five European sites (BD: Jul 2, 2026).

At the time, the company said the Pulse study was part of the Palacros, or 'Prioritizing Multimodal Surgical Care for Patients with Locally Advanced Pancreatic Cancer Across Europe' consortium, funded by the EU under the Horizon Europe research and innovation program to support clinical trials and improve patient selection.

Today, Oncosil said it would provide devices, with no additional study-related costs and the study opened in Amsterdam following an "official kick-off meeting ... for consortium partners to align on the program's objectives, research priorities and collaborative activities".

Oncosil managing-director Nigel Lange said the official launch of 'Palacros' in Amsterdam was "an important milestone in bringing together leading European institutions to advance pancreatic cancer research and treatment".

Oncosil was up 1.5 cents or 2.2 percent to 71 cents.

CLEO DIAGNOSTICS

Cleo says it has begun analytical validation of its pre-surgical ovarian cancer test following receipt of the first batch of 125 test kits from Bio-Techne Corp.

In April, Cleo said it had begun manufacturing and development with Minneapolis, Minnesota's Bio-Techne to produce its ovarian cancer test kits (BD: Apr 28, 2026).

Today, the company said the validation process was being conducted in-house using Bio-Techne's Ella automated immuno-assay platform, with the resulting data to be used to support its planned US Food and Drug Administration 510(k) submission.

Cleo said the second and third batch kits were expected to be received in November 2026, with the validation expected to take about three months.

The company it expected to submit an FDA 510(k) application by July 2027.

Cleo fell half a cent or 1.4 percent to 34.5 cents.

FLINDERS UNIVERSITY

Flinders University says it has opened a \$10 million genomics laboratory at its Bedford Park, Adelaide campus to improve health and agricultural discoveries.

Flinders University said the facility would “help Australian researchers better understand disease, develop more resilient crops and respond to environmental change by making large-scale sequencing faster and more affordable”.

The University said the genomics laboratory would “enable one of the highest-throughput and lowest-cost genomics capabilities in the Southern Hemisphere, with the capacity to sequence the equivalent of up to 59,000 complete human genomes each year”.

Flinders University said the facility was opened in partnership with the South Australian Genomics Centre (SAGC), Bioplatforms Australia and Decode Science and would operate as a national research resource for universities and research institutes.

The University said the facility was “designed to keep biological samples and genomic data secure and within Australia, supported by secure workflows, Australian-based data storage and independent cybersecurity review”.

Flinders University said to show its capability the laboratory planned to run a national competition offering eligible Australian universities and research institutes the opportunity to have a total of 5,000 human genomes sequenced at no cost, supported by Decode Science, with the competition expected to open “later this year”.

THE UNIVERSITY OF QUEENSLAND

The University of Queensland says it will conduct a 100-woman ‘Clarity’ trial of a potential non-invasive blood test for cervical cancer screening.

The University of Queensland said the trial would be conducted at the Royal Brisbane and Women’s Hospital to investigate the potential of blood bio-markers in the screening, monitoring and management of cervical cancer.

The University said the study would “contribute to the development of a novel, blood-based screening and monitoring tool that could enable earlier intervention and improve long-term outcomes”.

According to the University of Queensland website, the study would analyze blood samples to assess the role of blood bio-markers in tumor development, progression, and intercellular communication.

The University said the expected outcomes of the trial included the identification of blood-based signatures that could facilitate earlier detection of cervical cancer, enable real-time monitoring of treatment response, predict recurrence and disease progression and support the development of personalized therapeutics.

The University of Queensland said the study would generate “preliminary comparative data on the diagnostic accuracy of blood bio-markers” to provide a foundation for future large-scale investigations.

Chief study investigator Prof Andreas Obermair said the project had “the potential to improve early detection, treatment responses and post-treatment surveillance, as well as support more personalized treatment approaches for women with cervical cancer”.

“Despite advances in prevention and treatment, including the success of the Gardasil vaccine, cervical cancer continues to impose significant physical, emotional, and financial burdens on women worldwide,” Prof Obermair said. “A reliable, non-invasive test would also serve as a more accessible and acceptable alternative to current cervical screening methods, particularly for women who face cultural, systemic, or personal barriers.”

“This is especially important for under-screened populations, including Aboriginal and Torres Strait Islander women and culturally diverse communities.,” Prof Obermair said.

NYRADA INC

Nyrada says US Food and Drug Administration feedback was “supportive” of its proposed development pathway for Xolatryp in cardio-protection, with no major issues.

Nyrada said it had written FDA feedback in response to its pre-investigational new drug meeting request for its Xolatryp cardio-protection program.

The company said the FDA’s response followed a review of Xolatryp’s chemistry, manufacturing and controls information, non-clinical efficacy, safety, toxicology data, and clinical development briefing package.

Nyrada said the FDA indicated that its non-clinical safety program “appears sufficient in scope to support the phase IIa study and requested some additional information”, provided guidance on the potential use of existing non-clinical data to support subsequent clinical development and agreed in principle with the patient population.

The company said the FDA considered the planned safety monitoring measures appropriate and indicated that the overall clinical endpoint framework was reasonable.

Nyrada said the FDA acknowledged that myocardial infarction was a serious condition and indicated that a fast track designation request might be reasonable if a phase III trial evaluated clinical endpoints reflecting serious aspects of the condition.

The company said it remained on-track to submit its investigational new drug application by July 2027 to begin its phase IIa trial in the US.

Nyrada fell two cents or 4.2 percent to 46 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says the US Food and Drug Administration has agreed on the phase II trial design and sufficiency of previous data for Stemsmart in Crohn’s disease.

Last year, Neuroscientific said it had acquired Perth’s Isopogen and its Stemsmart technology (BD: Jun 27, 2025).

Today, the company said the FDA reviewed its clinical program briefing package and provided a “favorable response to six of the seven questions posed”.

Neuroscientific said the one matter the FDA required to be addressed was the control strategy for manufacturing, to ensure the product was free from viral contamination.

The company said it agreed “with the FDA’s feedback and is implementing the required testing with minimal impact to timelines”.

Neuroscientific chief executive officer Nathan Smith said the FDA response was “another pivotal milestone”.

Neuroscientific was up 0.1 cents or 1.7 percent to 5.9 cents.

IMMUTEP

Immutep says it has regained Nasdaq Listing Rule compliance after its closing bid price remained at or above \$US1.00 a share for 10 consecutive business days.

Earlier this year, Immutep said it had a Nasdaq notice that it did not meet the Listing Rule 5450(a)(1) requirements of a minimum bid price of \$US1.00 a share (BD: Apr 30, 2026).

At the time, the company said that if at any time during the compliance period the closing bid price of its American depository shares (ADS) was at least \$US1.00 a share for a minimum of 10 consecutive business days, the Nasdaq would notify it that compliance had been regained.

Today, Immutep said to address the deficiency it had increased its Australian shares to ADSs ratio from one-to-10 to one-to-200 (BD: Sep 21, 2026).

Immutep fell 0.1 cents or 3.7 percent to 2.6 cents with 10.3 million shares traded.

MESOBLAST

Mesoblast says its annual general meeting will vote to issue 3,329,000 options to its managing-director and chief medical officer and 671,295 restricted stock to its board. Mesoblast said investors would vote to issue managing-director Prof Silviu Itescu 1,950,000 long-term incentive options and 559,900 short-term incentive options, exercisable at \$2.16 each within seven years of the grant date.

The company said shareholders would vote to issue chief medical officer Dr Eric Rose 820,000 long-term incentive options under the same terms as Prof Itescu's, with the options subject to performance milestones.

Mesoblast said the options were in addition to Prof Itescu's \$US950,000 (\$A1,365,100) base yearly salary and Dr Rose's \$US627,300 (\$A901,399) annual base pay.

The company said it proposed to freeze existing cash fees for directors and introduce a yearly grant of restricted stock units with a value of \$290,000 for eligible directors.

Mesoblast said the meeting would vote to issue 134,259 restricted stock units, each, valued at \$290,000, to chair and Philip Facchina, as well as directors Jane Bell, Dr Philip Krause and Lynette Cobley.

Mesoblast said the meeting would vote on the remuneration report, to elect directors Mr Facchina and Mr Voigtman, approve the restricted stock unit plan and the employee share buy-back definition, as well as the issue of warrants to Dr Gregory George.

The meeting will be held at Minter Ellison, Collins Arch, Level 20, 447 Collins Street, Melbourne on November 10, 2026 at 9am (AEDT).

Mesoblast fell three cents or 1.5 percent to \$2.03 with 2.5 million shares traded.

LUMOS DIAGNOSTICS

Lumos says its annual general meeting will vote to issue 17,849,593 long-term performance rights to managing-director Doug Ward.

Lumos said that the rights were valued at \$1,999,155, in addition to Mr Ward's \$US499,550 (\$A717,671) base yearly salary and subject to operational and revenue-related milestones.

The company said shareholders would vote to adopt the remuneration report, elect directors Aizaz Syed and Catherine Robson, approve the issue of share purchase plan options, ratify the issue of placement shares and options, renew the company's long-term incentive plan and approve the 10 percent placement facility.

The meeting will be held online on November 13, 2026 at 9am (AEDT).

Lumos fell half a cent or 5.1 percent to 9.3 cents with 1.9 million shares traded.

BLS PHARMACEUTICALS (FORMERLY BIOXYNE)

Kirkman Trading Ltd says it has ceased its substantial shareholding in BLS with the sale of 15,780,560 shares on October 6, 2026 for \$17,832,032, or \$1.13 a share.

In 2023, the then Bioxyne said it acquired Gold Coast, Queensland's Breathe Life Sciences (BD: May 22, 2023).

Earlier this year, the company said its extraordinary general meeting had overwhelmingly approved both its change of company name to 'BLS Pharmaceuticals' and a 10-to-one consolidation (BD: Jun 22, 2026).

BLS was up 2.5 cents or 2.5 percent to \$1.04.

CERYVYN THERAPEUTICS (FORMERLY OPTHEA)

Jagen Nominees Pty Ltd says it has increased its substantial shareholding in Ceryvyn from 226,549,303 shares (16.56%) to 262,307,713 shares (19.17%).

Melbourne's Jagen said that the shares were held by BHL Pension Fund Pty Ltd acting for the B Liberman Family and Boliber Pty Ltd.

In 2018, Jagen said it became a substantial holder in Opthea with 18,202,068 shares (7.31%) and that it was an investment vehicle for Bori Liberman (BD: Dec 4, 2018).

Today, Jagen said it that between October 9 and 13, 2026 it bought 35,758,410 shares for \$455,179, or 1.3 cents a share.

Ceryvyn was unchanged at 1.1 cents with 5.15 million shares traded.